

| | | |
|--|----------------|--------------------|
| PRE-APPEAL BRIEF REQUEST FOR REVIEW | Application # | 08/981,665 |
| | Confirmation # | 8326 |
| | Filing Date | 11/05/1997 |
| | First Inventor | CIPKOWSKI |
| | Art Unit | 1641 |
| | Examiner | Grun, James Leslie |
| | Docket # | P08948US01/BAS |


Applicant requests review of the final rejection in the above-identified application.
No amendments are being filed with this request.

This request is being filed with a NOTICE OF APPEAL.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the Attorney of Record.

Date: March 26, 2010

Signed By 
Attorney of Record, Name: B. Aaron Schulman
Registration No.: 31,877

STITES & HARBISON PLLC ♦ 1199 North Fairfax St. ♦ Suite 900 ♦ Alexandria, VA 22314
TEL: 703-739-4900 ♦ FAX: 703-739-9577 ♦ CUSTOMER NO. 881

REMARKS AND ARGUMENTS IN SUPPORT OF PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicant respectfully requests reconsideration and withdrawal of the final rejection through a pre-appeal review that will show that the outstanding rejections are improper and should be withdrawn. There are only two substantive rejections remaining and in both cases, there is no support for the Examiner's position as explained in more detail below.

In the Final Rejection, the Examiner rejected Claims 16, 18 and 19 under 35 U.S.C. §112, first paragraph, for failure to comply with the written description requirement. The Examiner's ostensible basis for this rejection was that the specification does not provide support for

“a sample **contacting portion on the exposed surface** (i.e., front) **of the test strip** so that liquid sample flows through the sample opening in the thin flat member strip holder and contacts the **exposed surface** (i.e., front) of the sample portion directly beneath (i.e., registering with) the opening.”

See Final Rejection, page 2 (emphasis by Examiner). Such a position is completely unfounded since the specification unambiguously shows these features.

In short, Applicants' claimed invention as shown, e.g., in Fig. 1, relates to a thin flat test card for assaying drugs of abuse which contains a plurality of conventional test strips which are housed inside the test card. These test strips are placed flat inside the test card so that the sample contacting portion of the test strip is directly below an opening of the test card. This is clearly and unambiguously shown in Applicants' specification, e.g., page 12, lines 7-9 wherein it is disclosed that there are “sample openings 51 through which the liquid test specimen is able to contact the absorbent or sample portions of the test strips.” The fact that the test card has an opening at the test portion and the sample portion with the underlying regions of the test strip exposed through said openings is specifically disclosed at page 11, lines 18-20 wherein the specification states that in the modified test card of Fig. 9, “the test strips are covered but the pertinent test and sample portions of the test strips are exposed through openings.” This pattern is also shown in the modified version disclosed as Fig. 11.

Accordingly, there is no question that the claimed subject matter is fully and completely described in the specification and moreover, the Examiner's only position appears to be based on his own confusion regarding what Applicant meant by "conventional test strip." A conventional test strip, as shown in the specification and drawing figures, is a long thin flat strip that fits into the test card such that the sample contacting portion of the test strip is directly below a corresponding opening in the test card. Compare Figs. 11 (test card over the test strips) and 12 (showing of test strips below front of test card). This is not extremely complex, but rather very plain and simple. The drawing figures and specification disclose the invention exactly as claimed. The Examiner's rejection under the written description requirement of Section 112 is completely unfounded and should be withdrawn.¹

In the Final Rejection, the Examiner rejected Claims 16, 18 and 19 under 35 U.S.C. §103 as obvious over May et al. PCT application WO 88/08534 in view of Sun et al. (US 5,238,652) and further in view of Boger et al. US 4,518,565. However, in light of the fact that none of these references disclose the claimed invention nor can be combined to come up with the claimed invention, this rejection is also unfounded as is explained further below.

As indicated above, it appears that the actual rejection is based on the Examiner's confusion with the claimed invention, which is a test card, as opposed to the Examiner's repeated focus on the test strips therein which are conventional elements and not reflective of the improvements provided by the present invention. In the Final Rejection, the Examiner's main points for maintaining the rejection was that (1) Applicant admitted that test strips were commercially available (see Final Rejection, bottom of Page 7, "Applicant also clearly admits that the test strips for performance were commercially available."); and (2) that Applicants' arguments have "attacked the references individually" and thus cannot show unobviousness when the rejections are based on combinations (see start of second full paragraph on Page 7).

¹ There is a minor objection to Claim 16 in that the word "the" before "fluid sample" should be replaced by the word "a". Applicants would consent to this change as an Examiner's amendment if so required.

In fact, Applicant's claims are not directed to a test strip but a test card, and Applicant's have not "attacked the references individually" but instead have shown conclusively that those references, either singly or in combination, nowhere disclose or make obvious in any way a test card containing features in accordance with the claimed invention, and to the contrary **teach away** from the claims.

With regard to the Examiner's reference to the fact that "Applicant clearly admits that the test strips for performance of the immunoassay were commercially available", this is not rocket science as Applicant's disclosure plainly states that these test strips are conventional (e.g., see bottom of page 8 to top of page 9 where Applicant states "Test strips 26-30 may be of the type as made by Bionike of South San Francisco, California, Pharmatech of San Diego, California and Arista Biological of Bethlehem, Pennsylvania.") Once again, by focusing on the conventional test strips, the Examiner has missed the points of distinction over the prior art which have nothing to do with the strips and everything to do with the specific configuration of the test card as described in Applicant's claims. As shown below, indeed neither the cited May reference, nor the other citations Sun and Boger, disclose or suggest the claimed invention either singly or in combination.

In fact, the Examiner's repeated allegation that Applicant is "attacking the references individually" when in fact the rejections were based on a combination of references (see, e.g., page 7, start of second paragraph) also reflects that the Examiner has not made a proper rejection. While this general principle may be appropriate wherein the Examiner has located elements of the claimed invention in two different references and then argues that the combination of the two references makes the invention obvious, it is **not** appropriate in the case where, as here, the Examiner has not shown that the essential elements of the claimed invention are located in **any** reference, much less in a combination of references. For example, an obviousness rejection to a claimed combination of A and B may be appropriate when the

Examiner cites reference 1 showing "A" and reference 2 showing "B", and then provides a reason why one skilled in the art would combine the two.

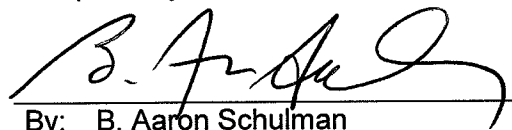
However, **this is not the case with the Examiner's current rejections.** To the contrary, the Examiner is citing the May reference (WO 88/08534), the Sun reference (US patent 5,238,652) and the Boger reference (US 4,518,565), **none of which disclose the specific test card of the present invention**, namely one wherein the test card houses one or more immunoassay strips wherein the liquid specimen passes through the opening directly above the sample contacting portion on the front of the test strip and then proceeds via capillary action along the strip to the test portion wherein an analyte in the specimen may be visually determined through another opening in the test card. To the contrary, the May reference **teaches away** from the present claims because the device disclosed therein **covers up** in all cases the front surface of the test strip and **prevents** the sample from contacting the test strip on the front surface of the strip. Instead, the May reference (as well as the cited Sun reference) discloses a test card wherein there is a sample opening which only exposes the end of a porous member through which the specimen must pass before it can even contact the absorbent part of the test strip, and thus this reference directs one skilled in the art **away** from the present invention because only the lower edge of a test strip is contacted with the fluid sample.

Moreover, the Examiner cites the Boger et al. reference for the fact that Boger shows "ridges or other means which facilitate the preferred parallel alignment of the strips". However, Boger is totally unrelated to the present invention and does not disclose or suggest **any** immunoassay test strip whatsoever. Instead, Boger involves applying the test sample to a reagent pad or spot, a wholly different test than the immunoassay conducted in accordance with the test card of the present application. The Examiner's description of the Boger et al. reference once again concedes that this reference also does not disclose or suggest Applicant's claimed features.

The Examiner thus cannot make a proper rejection based on a combination of reference when **there is nothing to combine** from the May and Boger references which would together disclose the elements of the present claims directed to a test card, much less make those features obvious. To the contrary, as set forth above, the May reference teaches an immunoassay device that operates in a manner that is **completely opposite** to the manner of operation of Applicant's test card, namely one in which the front surface of the immunoassay test strip is **blocked** from receiving a sample and the sample can **only** contact the test strip from a lower edge. Instead, Applicant's invention specifically **avoids** and **overcomes** the problems associated with the prior art immunoassay test devices such as shown in May by having a sample contacting portion in the test card whereby the sample can directly contact the front surface portion of the test strip. Since there is nothing in the other references which discloses or remotely suggests Applicant's test card, these references do not, either singly or in combination, disclose or suggest Applicant's claimed invention, and indeed since the device of May acts in a manner to **prevent** an embodiment of the type set forth in Applicant's claims, the prior art actually **teaches away** from the present invention.

For the reasons as stated above, in combination with Applicant's arguments as reflected in the record, Applicant submits that the outstanding rejections are improper and should be withdrawn, and that this application should be passed on for immediate allowance. Such action is respectfully requested.

Respectfully submitted,



By: B. Aaron Schulman
Registration No.: 31,877

Date: March 26, 2010

STITES & HARBISON PLC ♦ 1199 North Fairfax St. ♦ Suite 900 ♦ Alexandria, VA 22314
TEL: 703-739-4900 ♦ FAX: 703-739-9577 ♦ CUSTOMER NO. 000881